Each milliliter contains sisomicin sulfate equivalent to 50 milligrams of sisomicin. Its potency is satisfactory if it contains not less than 90 percent and not more than 120 percent of the number of milligrams of sisomicin that it is represented to contain. It is sterile. It is nonpyrogenic. Its pH is not less than 2.5 and not more than 5.5. The sisomicin sulfate used conforms to the standards prescribed by § 444.62(a)(1).

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 432.5 of this chapter.

(3) *Requests for certification; samples.* In addition to complying with the requirements of § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The sisomicin sulfate used in making the batch for potency, loss on drying, pH, residue on ignition, specific rotation, and identity.

(*b*) The batch for potency, sterility, pyrogens, and pH.

(ii) Samples required:

(*a*) The sisomicin sulfate used in making the batch: 12 packages, each containing approximately 500 milligrams.

(*b*) The batch:

(*1*) For all tests except sterility: A minimum of 12 vials.

(*2*) For sterility testing: 20 immediate containers collected at regular intervals throughout each filling operation.

(b) *Tests and methods of assay*—(1) *Potency.* Proceed as directed in § 436.105 of this chapter, preparing the sample for assay as follows: Dilute an accurately measured representative portion of the product with 0.1*M* potassium phosphate buffer, pH 8.0 (solution 3), to the reference concentration of 0.1 microgram of sisomicin per milliliter (estimated).

(2) *Sterility.* Proceed as directed in § 436.20 of this chapter, using the method described in paragraph (e)(1) of that section.

(3) *Pyrogens.* Proceed as directed in § 436.32(a) of this chapter, using a solution containing 10 milligrams of sisomicin per milliliter.

(4) [Reserved]

(5) *pH.* Proceed as directed in § 436.202 of this chapter, using the undiluted solution.

[46 FR 2989, Jan. 13, 1981, as amended at 50 FR 19919, May 13, 1985]

§ 444.270 Streptomycin sulfate injectable dosage forms.

§ 444.270a Sterile streptomycin sulfate.

The requirements for certification and the tests and methods of assay for sterile streptomycin sulfate, packaged for dispensing, are described in § 444.70a.

[42 FR 21275, Apr. 26, 1977]

§ 444.270b Streptomycin sulfate injection.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Streptomycin sulfate injection is an aqueous solution of streptomycin sulfate. It may contain one or more suitable and harmless preservatives, buffer substances and stabilizing agents. Each milliliter contains streptomycin sulfate equivalent to 400 milligrams, 420 milligrams, or 500 milligrams of streptomycin. Its potency is satisfactory if it is not less than 90 percent and not more than 115 percent of the number of milligrams of streptomycin that it is represented to contain. It is sterile. It is nonpyrogenic. It contains no depressor substances. Its pH is not less than 5.0 and not more than 8.0. The streptomycin sulfate used conforms to the standards prescribed by § 444.70a(a)(1).

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 432.5 of this chapter.

(3) *Requests for certification; samples.* In addition to complying with the requirements of § 431.1 of this chapter, each such request shall contain;

(i) Results of tests and assays on:

(*a*) The streptomycin sulfate used in making the batch for potency, depressor substances, loss on drying, pH, and identity.

(*b*) The batch for potency, sterility, pyrogens, depressor substances (except that the results of this test performed on the streptomycin sulfate used in making the batch may be submitted instead), and pH.

(ii) Samples required:

(*a*) The streptomycin sulfate used in making the batch: 10 packages, each containing approximately 500 milligrams.

(*b*) The batch:

(*1*) If the batch is packaged for use in the manufacture of another drug:

(*i*) For all tests except sterility: Five containers, each containing not less than 2.0 milliliters.

(*ii*) For sterility testing: 20 containers, each containing not less than 2.0 milliliters.

(*2*) If the batch is packaged for dispensing:

(*i*) For all tests except sterility: A minimum of eight immediate containers.

(*ii*) For sterility testing: 20 immediate containers, collected at regular intervals throughout each filling operation.

(b) *Tests and method of assay*—(1) *Potency*. Proceed as directed in § 436.106 of this chapter, preparing the sample for assay as follows: Using a suitable hypodermic syringe and needle, remove all of the withdrawable contents if it is represented as a single-dose container; or if the labeling specifies the amount of potency in a given volume of the resultant preparation, remove an accurately measured representative portion from each container. Accurately dilute the portion with sterile distilled water to give a stock solution of convenient concentration. Further dilute an aliquot of the stock solution with sterile distilled water to the reference concentration of 30 micrograms of streptomycin per milliliter (estimated).

(2) *Sterility*. Proceed as directed in § 436.20 of this chapter, using the method described in paragraph (e)(1) of that section.

(3) *Pyrogens.* Proceed as directed in § 436.32(b) of this chapter, using a solution containing 10 milligrams of streptomycin per milliliter.

(4) [Reserved]

(5) *Depressor substances* (the depressor substances test may be omitted if it is performed on the streptomycin sulfate used in preparing the injection). Proceed as directed in § 436.35 of this chapter.

(6) *pH*. Proceed as directed in § 436.202 of this chapter, using the undiluted solution.

[42 FR 21275, Apr. 26, 1977; 42 FR 37543, July 7, 1977, as amended at 46 FR 60568, Dec. 11, 1981; 50 FR 19919, May 13, 1985]

§ 444.280 Tobramycin sulfate injection.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity*. Tobramycin sulfate injection is tobramycin solubilized with sulfuric acid in an aqueous solution containing one or more suitable buffers, chelating agents, and preservatives. Each milliliter contains tobramycin sulfate equivalent to either 10 milligrams or 40 milligrams of tobramycin. Its potency is satisfactory if it contains not less than 90 percent and not more than 120 percent of the number of milligrams of tobramycin that it is represented to contain. It is sterile. It is nonpyrogenic. Its pH is not less than 3.0 and not more than 6.5. The tobramycin used conforms to the standards prescribed by § 444.80(a)(1).

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 432.5 of this chapter.

(3) *Requests for certification; samples.* In addition to the requirements of § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The tobramycin used in making the batch for potency, moisture, pH, identity, residue on ignition, and heavy metals.

(*b*) The batch for potency, sterility, pyrogens, and pH.

(ii) Samples required:

(*a*) The tobramycin used in making the batch: 10 packages, each containing approximately 500 milligrams.

(*b*) The batch:

(*1*) For all tests except sterility: A minimum of 40 vials if each milliliter contains 10 milligrams of tobramycin per milliliter, or a minimum of 12 vials if each milliliter contains the equivalent of 40 milligrams of tobramycin.

(*2*) For sterility testing: 20 immediate containers, collected at regular intervals throughout each filling operation.

(b) *Tests and methods of assay*—(1) *Potency*. Proceed as directed in § 436.106 of this chapter, preparing the sample for assay as follows: If the immediate container is a single-dose vial, use a suitable hypodermic needle and syringe and remove all the withdrawable contents; or, if the labeling specifies the amount of potency in a given volume,